Severe Drug Shortages Impose Heavy Costs on Hospital Pharmacies

Senate Bill Might Help … or Not

Stephen Barlas

Paul Allen, PharmD, has been a hospital pharmacist for 25 years. As Associate Vice President of Pharmacy Services at Norton Healthcare, Inc., in Louisville, Ky., he says that he has never seen the drug shortage situation so severe. An analysis published by the Premier Healthcare Alliance in March 2011 claimed that over the course of a six-month period in 2010 (from July to December), more than 240 drugs were either in short supply or completely unavailable, and more than 400 generic varieties had been back-ordered for five or more days.

After contacting 311 hospital pharmacy experts representing 228 hospitals, Premier estimated the shortage was costing hospitals in the U.S. at least $200 million annually because of the need to purchase more expensive generic or therapeutic substitutes. That estimate does not include indirect costs, such as the added labor needed to manage shortages and to secure alternative supplies; data regarding these aspects of the problem do not exist.

That is why many hospital pharmacists around the country are hoping that new legislation introduced in the Senate will at least ameliorate the current shortage. The bill, called the Preserving Access to Life-Saving Medications Act (S. 296), was introduced by Senators Amy Klobuchar (D-Minn.) and Bob Casey (D-Pa.) at the behest of groups such as the American Society of Clinical Oncologists, the American Society of Anesthesiologists, and the American Society of Health-System Pharmacists (ASHP). The bill would require prescription drug manufacturers to give early notice to the FDA of any incident that would be likely to result in a drug shortage. The FDA would have the authority to set a schedule of civil penalties to be applied if the manufacturer has not notified the agency as required.

Currently, some drug companies do voluntarily alert the FDA to anticipated shortages. Karen Mahoney, an FDA spokesperson, explains that during 2010, 38 shortages were prevented through early notification from the firms. When the FDA receives notice of a future shortage, it can choose from several options to mitigate the problem, such as allowing the temporary importation of still unapproved alternative medications.

George Hill, RPh, MBA, Director of Pharmacy at Catholic Health Initiatives in Erlanger, Ky., gives a lot of credit to Valerie Jensen, head of the FDA’s drug shortage office, for keeping him and Catholic Health Initiative’s 73 hospitals around the country apprised of what is going on in the drug-supply chain.

“You can hear a lot of negative things about the FDA, but I have to give them some positive kudos,” he says.

Of course, not all drug shortages are equal. For example, Ernest R. Anderson, Jr., MS, Vice President of Pharmacy at Steward Health Care in Massachusetts, recently received an e-mail from a pharmacy director at one of Steward’s six Boston-area hospitals. The e-mail stated that owing to a nationwide shortage of dexamethasone injection, Steward was temporarily removing the dexamethasone order from the Lap-Band order set, which also includes other antinausea agents.

The impact can be much more serious, of course, with shortages of everything from anesthesia drugs to oncolytic agents such as cytarabine liposome injection (DepoCyt, Enzon), which many hospitals cannot obtain. In fact, intravenous (IV) oncology medications top the list of drugs in short supply, perhaps because they are more likely to be subject to discontinuations resulting from violations of Good Manufacturing Practice (GMP) cited by the FDA. Halted production often results in plant closures. In 2010, manufacturing problems forced Hospira to recall AstraZeneca’s propofol (Diprivan).

“Some of my colleagues were close to shutting down operating rooms,” reports Robert J. Bepko Jr., RPh, MHA, Director of Professional Services at Norwalk Hospital in Connecticut.

In the case of propofol, the FDA allowed APP’s Fresenius Propoven 1% (propofol 1%) to be imported temporarily; however, this alternative medication does not contain an antimicrobial retardant such as ethylene diaminetetraacetic acid (EDTA), sodium metabisulfate, or benzyl alcohol/sodium benzoate. As such, strict aseptic technique must always be maintained during handling.

Epinephrine can be used instead of norepinephrine bitartrate injection (Levophed, Hospira), a blood pressure medication, one of the many drugs in short supply these days. However, epinephrine has different physiological effects and is not always an ideal replacement, according to Mr. Anderson.

Senator Klobuchar’s bill would give hospital pharmacists more time to plan for anticipated shortages. Right now, there is no indication that the Senate Health, Education, Labor and Pensions Committee, where the bill had been referred, will be taking up this legislation. So far, the bill has only Democratic cosponsors—and no one in the House of Representatives has introduced a companion bill.

Pharmaceutical Research and Manufacturers of America (PhRMA) is likely to oppose the bill. And with Republican control of the House, the bill’s chances there—given normally strong GOP support for PhRMA—might not be all that

continued on page 302
good. Joel Gross, Senator Klobuchar’s press secretary, did not respond to a message asking for input on the bill’s legislative prospects.

Even those in the hospital pharmacy community who support the Klobuchar bill say only that it would be a good first step. Others are not even convinced that the bill would help. Mr. Bepko thinks that mandatory early notification would play into the hands of gray-market distributors, who already have ways of quickly learning about presumed shortages and who snap up these scarce drugs; this complicates life for hospital pharmacists, who cannot really be sure about the actual source of gray-market drugs.

“As soon as we get notification from the FDA or a manufacturer about a shortage, the next thing is [that] faxes start flowing in from gray market distributors offering those drugs,” says Mr. Bepko.

REFERENCE